

CLAIMS

We claim:

1. Paroxetine hydrochloride anhydrate substantially free of bound propan-2-ol.
- 5 2. Paroxetine hydrochloride anhydrate substantially free of bound organic solvent.
3. Paroxetine hydrochloride anhydrate substantially free of bound propan-2-ol with the proviso that it is other than Form Z.
- 10 4. Paroxetine hydrochloride solvates other than the propan-2-ol solvate.
5. Paroxetine hydrochloride solvates as defined in claim 4 wherein the solvate is selected from the group consisting of alcohols (other than propan-2-ol),
15 organic acids, organic bases, nitriles, ketones, ethers, chlorinated hydrocarbons and hydrocarbons.
6. Paroxetine hydrochloride solvate as defined in claim 4 wherein the solvate is selected from the group consisting of propan-1-ol, ethanol, acetic acid,
20 pyridine, acetonitrile, acetone, tetrahydrofuran, chloroform and toluene.
7. Paroxetine hydrochloride anhydrate substantially free of bound propan-2-ol in substantially pure form.
- 25 8. Paroxetine hydrochloride anhydrate as defined in claim 1 in Form A; which is characterized in that it has a melting point of about 123-125°C and has significant IR bands at about 513, 538, 571, 592, 613, 665, 722, 761, 783, 806, 818, 839, 888, 906, 924, 947, 966, 982, 1006, 1034, 1068, 1091, 1134, 1194, 1221, 1248, 1286, 1340, 1387, 1493, 1513, 1562, 1604, 3402, 3631 cm^{-1} and the
30 DSC exotherm, measured at 10°C per minute shows a maximum at about 126°C using an open pan and a maximum at about 121°C using a closed pan; it also has a substantially similar X-ray diffractogram to that shown in Figure 4, including characteristic peaks at 6.6, 8.0, 11.2, 13.1 degrees 2 theta and a substantially similar solid state ^{13}C -NMR spectrum to that shown in Figure 7 including with
35 characteristic peaks at 154.3, 149.3, 141.6, 138.5 ppm.

9. Paroxetine hydrochloride anhydrate as defined in claim 1 in Form B; which is characterized in that it has a melting point of about 138°C and has significant IR bands at about 538, 574, 614, 675, 722, 762, 782, 815, 833, 884,
5 925, 938, 970, 986, 1006, 1039, 1069, 1094, 1114, 1142, 1182, 1230, 1274, 1304, 1488, 1510, 1574, 1604, 1631 cm⁻¹; the DSC exotherm, measured at 10°C per minute, shows a maximum of about 137°C in both open and closed pans; it also has a substantially similar X-ray diffractogram to that shown in Figure 5, including characteristic peaks at 5.7, 11.3, 12.4, 14.3 degrees 2 theta and a
10 substantially similar solid state ¹³C-NMR spectrum to that shown in Figure 8, including characteristic peaks at 154.6, 148.3, 150.1, 141.7, 142.7, 139.0 ppm.
10. Paroxetine hydrochloride anhydrate as defined in claim 1 in Form C; which is characterized in that it has a melting point of about 164°C and it has
15 significant IR bands at about 540, 574, 615, 674, 720, 760, 779, 802, 829, 840, 886, 935, 965, 984, 1007, 1034, 1092, 1109, 1139, 1183, 1218, 1240, 1263, 1280, 1507, 1540, 1558, 1598, 1652 cm⁻¹; the DSC exotherm, measured at 10°C per minute, shows a maximum of about 161°C in both open and closed pans; it also has a substantially similar X-ray diffractogram to that shown in Figure 6
20 including characteristic peaks at 10.1, 12.1, 13.1, 14.3 degrees 2 theta and a substantially similar solid state ¹³C-NMR spectrum to that in Figure 7, including characteristic peaks at 154.0, 148.5, 143.4, 140.4 ppm.
11. Paroxetine hydrochloride anhydrate as defined in claim 1 in Form D;
25 which is characterized in that it exists as a semi-crystalline solid with a melting point of about 125°C and is also characterized in that it has essentially similar physical characteristics when prepared from a toluene precursor solvate using methods generally described herein said toluene precursor solvate having significant IR bands at about 1631, 1603, 1555, 1513, 1503, 1489, 1340, 1275,
30 1240, 1221, 1185, 1168, 1140, 1113, 1101, 1076, 1037, 1007, 986, 968, 935, 924, 885, 841, 818, 783, 760, 742, 720, 698, 672, 612, 572, 537 and 465 cm⁻¹, and characteristic X-ray diffraction peaks at 7.2, 9.3, 12.7 and 14.3 degrees 2 theta.

12. Paroxetine hydrochloride anhydrate as defined in claim 1, which is in the form of needles or prisms.
13. Paroxetine hydrochloride anhydrate as defined in claim 8, which is in the
5 form of needles.
14. Paroxetine hydrochloride anhydrate as defined in claim 9, which is in the form of needles.
- 10 15. Paroxetine hydrochloride anhydrate as defined in claim 10, which is in the form of needles or prisms.
16. A compound as defined in claim 1 which is selected from the group consisting of crystalline paroxetine hydrochloride anhydrate substantially free of
15 bound pyridine (Form A), paroxetine hydrochloride anhydrate substantially free of bound acetic acid (Form A), paroxetine hydrochloride anhydrate substantially free of bound acetonitrile (Form A), paroxetine hydrochloride anhydrate (Form B), paroxetine hydrochloride anhydrate (Form C), paroxetine hydrochloride anhydrate substantially free of bound acetone (Form A), paroxetine hydrochloride
20 anhydrate substantially free of bound ethanol (Form A), paroxetine hydrochloride anhydrate substantially free of bound chloroform (Form A), paroxetine hydrochloride anhydrate (Form C), paroxetine hydrochloride anhydrate substantially free of bound propan-1-ol (Form A), paroxetine hydrochloride anhydrate (Form D), and paroxetine hydrochloride anhydrate substantially free of
25 bound tetrahydrofuran (Form A).
17. A compound as defined in claim 2 which is selected from the group consisting of crystalline paroxetine hydrochloride anhydrate substantially free of
bound pyridine (Form A), paroxetine hydrochloride anhydrate substantially free
30 of bound acetic acid (Form A), paroxetine hydrochloride anhydrate substantially free of bound acetonitrile (Form A), paroxetine hydrochloride anhydrate (Form B), paroxetine hydrochloride anhydrate (Form C), paroxetine hydrochloride anhydrate substantially free of bound acetone (Form A), paroxetine hydrochloride anhydrate substantially free of bound ethanol (Form A), paroxetine hydrochloride
35 anhydrate substantially free of bound chloroform (Form A), paroxetine

hydrochloride anhydrate (Form C), paroxetine hydrochloride anhydrate substantially free of bound propan-1-ol (Form A), paroxetine hydrochloride anhydrate (Form D), and paroxetine hydrochloride anhydrate substantially free of bound tetrahydrofuran (Form A).

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18. A compound as defined in claim 3 which is selected from the group consisting of crystalline paroxetine hydrochloride anhydrate substantially free of bound pyridine (Form A), paroxetine hydrochloride anhydrate substantially free of bound acetic acid (Form A), paroxetine hydrochloride anhydrate substantially free of bound acetonitrile (Form A), paroxetine hydrochloride anhydrate (Form B), paroxetine hydrochloride anhydrate (Form C), paroxetine hydrochloride anhydrate substantially free of bound acetone (Form A), paroxetine hydrochloride anhydrate substantially free of bound ethanol (Form A), paroxetine hydrochloride anhydrate substantially free of bound chloroform (Form A), paroxetine hydrochloride anhydrate (Form C), paroxetine hydrochloride anhydrate substantially free of bound propan-1-ol (Form A), paroxetine hydrochloride anhydrate (Form D), and paroxetine hydrochloride anhydrate substantially free of bound tetrahydrofuran (Form A).

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19. A process for the preparation of paroxetine hydrochloride anhydrate substantially free of propan-2-ol which comprises crystallizing paroxetine hydrochloride in either;

i) an organic solvent or mixture of organic solvents which form a solvate with the paroxetine hydrochloride and which are not removable by conventional drying techniques; or

ii) an organic solvent or mixture of organic solvents which do or do not form a solvate with the paroxetine hydrochloride but which are removable by conventional vacuum oven drying;

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thereafter in the case of i) displacing the solvated solvent or solvents using a displacing agent and in the case of ii) by removing the solvent.

20. A process for the preparation of the paroxetine hydrochloride solvates other than the propan-2-ol solvate which comprises crystallizing paroxetine hydrochloride in an organic solvent or mixture of solvents which form a solvate with the paroxetine hydrochloride and which are not removable by conventional drying techniques.
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21. A process for the preparation of paroxetine hydrochloride anhydrate substantially free of bound organic solvent which comprises displacing the solvated solvent or solvents from a paroxetine hydrochloride solvate using a displacing agent.
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22. A method for treating or preventing any one or more of the Disorders by administering an effective therapeutic or prophylactic amount of the products of the invention to a patient in need thereof.
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23. A pharmaceutical composition comprising the compound of claim 1 and a pharmaceutically acceptable carrier.
24. A pharmaceutical composition comprising the compound of claim 2 and a pharmaceutically acceptable carrier.
- 20
25. A pharmaceutical composition comprising the compound of claim 3 and a pharmaceutically acceptable carrier.